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Mr. Robert Wyatt
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RE: (DRAFT) PCB in Breast Milk at Portland Harbor

Dear Messrs. Wyatt and McKenna:

The U.S. Enivronmental Protection Agency (EPA) has asked the Environmental Health Assessment Program (EHAP, formerly SHINE) to develop recommendations on how to address the health risks for infants exposed to PCBs in breast milk in the context of the many health benefits of breast feeding. This health consultation is designed to answer their request.

Background

Resident fish species collected within Portland Harbor have been found to contain levels of polychlorinated biphenyls (PCBs) that may pose a risk to human health. For example PCB levels of up to 4.5 and 6.5 mg/kg have been detected in smallmouth bass tissue and carp tissue samples collected from Portland Harbor respectively. Consuming resident fish species from the harbor has been declared a public health hazard, and correlated fish advisories have been issued[1]. The current fish advisory includes the following clause: "Women of childbearing age, especially women who are pregnant, thinking about getting pregnant or nursing, infants and children and people with weak immune systems, thyroid or liver problems, should avoid eating resident fish from Portland Harbor. Examples of resident fish include bass, carp and bullhead catfish."[1]

Despite the current advisory, subsistence fishing from the harbor may occur although the extent to which it occurs is unknown. Without considering the health benefits of breast milk, preliminary estimates suggest that PCB levels in the milk of a woman eating fish resident to Portland Harbor could pose a health risk to nursing infants (See attached EPA draft risk assessment).

The breast feeding exposure pathway for environmental contaminants presents unique challenges to the health/risk assessor and public health officials. In most health/risk assessments, the exposure medium is considered only a delivery vehicle for the contaminant of concern. In the case of breast

milk, however, the exposure medium contains a multitude of healthful compounds that have been well documented to produce measurable health benefits. In fact, not breast feeding is considered a risk factor for several acute and chronic health conditions. Therefore, treatment of this exposure pathway requires not a simple assessment of risk, but rather, a balancing of the risks associated with contaminant exposure against the well documented health benefits of breast feeding. To further complicate this process, there is no accepted threshold value for PCBs in breast milk. In the absence of such thresholds, local, state, and federal health agencies struggle to formulate an appropriate public health response to this potential threat.

Discussion

Health benefits of breast feeding-

Breast feeding has been shown to be the healthiest option for infants under most conditions. Breast milk is an inexpensive, ideally balanced source of nutrition[2]. The infant immune system is matured and bolstered by breast milk components. Immunoglobulin A (IgA) in breast milk reduces the uptake of dietary antigens, protecting against development of food allergies[3]. IgA in breast milk also protects the infant against microbes from the maternal gut and prevents microbes from binding to the intestinal mucosal surface[4]. Breast milk also has anti-inflammatory properties, stimulates maturation of the intestinal epithelium and enhances the protective character of the intestinal mucosa[5]. This overall enhancement of immune function means reduced risk of multiple types of infectious disease for the infant.

Breast feeding is also associated with improved IQ scores and neurological development and reduced risk of SIDS, type I and type II diabetes, leukemia, obesity, asthma, and high cholesterol[2]. Recent research suggests that exclusive breast feeding may reduce the risk of celiac disease[6]. There are also psychological benefits to the improved mother-infant bonding that accompanies consistent breast feeding. Overall, non-breast-fed babies have a 21 percent higher mortality rate than breast-fed babies[2].

Mothers who breast feed also enjoy health benefits including reduced postpartum bleeding, reduced risk of breast and ovarian cancer, easier loss of excess adipose accumulated during pregnancy, and enhanced psychological well-being with increased bonding between mother and child. Breast feeding also benefits society by reducing health care costs (healthier babies), increasing worker productivity (children sick less often), and introduces less waste into the environment[2].

How does the estimated PCB dose to infants via breast milk compare with dose responses observed in animals?

Despite the documented benefits of breast feeding, breast milk may also contain environmental contaminants such as PCBs. PCBs may accumulate in the adipose tissue of mothers who are exposed to them. Upon lactation, body lipids and PCBs accumulated there over the course of several years are mobilized and secreted into milk. If a mother were to consume 142 g/day* (5 ounces/day) of small-mouth bass from Portland Harbor, EPA calculations estimated breast milk PCB levels in

* Ingestion rate determined based on EPA's Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2003). Document available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf.

excess of 38 µg/g-lipid (See attached EPA draft risk assessment).

An infant nursing from a mother with 38 µg/g-lipid PCBs in her milk is estimated to get 0.1 mg/kg/day. In other media, adverse health effects would be expected at this dose because it is 20 times higher than the lowest dose (0.005 mg/kg/day) shown to cause health effects in monkeys. Health effects that occurred in monkeys at this dose include altered finger and toe nails and nail beds, inflammation of eye-lid glands, and decreased immunity[7].

The estimated 0.1 mg/kg/day PCB dose to infants is slightly higher than the lowest levels (0.02-0.08 mg/kg/day) that caused more serious health effects in monkeys. These included decreased platelet volume, increased eye exudate, severely altered finger and toenails, and decreased performance in spatial learning memory and discrimination problem tests[7].

The 0.1 mg/kg/day PCB dose is about equal to the lowest levels (0.1-0.2 mg/kg/day) shown to cause more severe health effects in monkeys. These include hair and nail loss, anemia, liver damage, swelling of the cells in the gall bladder and biliary duct, facial edema, conjunctivitis, gingival necrosis, and thyroid desquamation[7].

How does the estimated PCB concentration in breast milk compare measured breast milk concentrations and associated health effects in nursing human children?

The EPA estimate of breast milk PCB concentration (38 µg/g-lipid) exceeds documented levels measured in human breast milk. Levels reported in the literature range from approximately 0.16 – 4 µg/g-lipid[8,9,10,11,12,13,14,15,16] with one study approaching levels as high as 10-15 µg/g-lipid[10]. Most studies found subtle health effects (see table) in children including deficits in composite activity rating[8] and performance on standardized neurocognitive tests[12,14,15,16].

Breast milk concentration (µg/g-lipid)	Health Effects	Study/Source	Comparison with formula-fed controls
≥0.78	Reduced composite activity rating	Jacobson[8]	No comparison
0.43 mean (0.17-0.749)*	Negative correlation with performance (7-month-old infants) on Bayley MDI, a standardized test to assess mental development	Winneke[16]	No comparison
0.43 mean	Negative correlation with neurological optimality scores at 21 days and with Bayley mental development index (MDI) and psychomotor Index (PDI) at 7 months of age. All deficits resolved by 18 months of age.	Schantz[15]	Breast-fed children did better than formula-fed in all parameters tested.
*5%-95% of breast milk samples			

In most cases, toxicity was attributed to prenatal exposure to PCBs. One study, known as the "Dutch PCB/Dioxin Study," compared the neurological performance of children exposed to PCBs only prenatally with that of children exposed prenatally and postnatally via breast milk. While children consuming milk containing higher PCBs fared worse than children consuming milk with lower levels, all groups of breast-fed children fared better than bottle-fed children. The lowest performing children had been exposed to high levels of PCBs prenatally but had been formula fed after birth. This seems to suggest that breast feeding, even with PCB-contaminated milk, served to counter the negative effects of prenatal PCB exposure[12,13,15]. The majority of studies conclude that, even with moderate contaminant levels, the health benefits of breast feeding still outweigh the risks associated with contaminant exposure.

Estimated breast milk PCB concentrations related to Portland Harbor (38 µg/g-lipid), however, exceed moderate background levels (0.16 – 4 µg/g-lipid) by as much as 237 fold. The highest measured PCBs in breast milk that EHAP was able to find were 15 µg/g-lipid[10]. While this study by Hara, et. al.[10] identified more health effects in children who breast-fed for more than 5 months from mothers with extensive occupational PCB exposure histories, these effects were self-reported, and none of the children were diagnosed as having PCB poisoning by health care professionals.

Risk vs. Benefit-

If a PCB dose of 0.1 mg/kg/day (See attached EPA draft risk assessment) were estimated in any other media, EHAP would recommend that citizens reduce or eliminate their exposure to that medium. However, PCB exposure via breast milk necessarily follows additional prenatal exposures during critical developmental windows. Studies cited here suggest that breast milk, even with significant PCB contamination, may serve to reverse or stabilize developmental lesions initiated by prenatal exposure[12,14].

The primary goal for environmental and health agencies should be to reduce PCB exposure to women of childbearing age. These findings reinforce the importance of current fish advisories issued by Oregon's Office of Environmental Public Health[1]. However, the recommended course for infants who have already had prenatal exposure to PCBs is clear. Breast feeding is best for infants regardless of PCB levels in the milk.

Affected population and EHAP activities- In regards to the Portland Harbor superfund site, the affected population (subsistence fish eaters who are pregnant, planning on becoming pregnant, or nursing) includes hard-to-reach ethnic communities. Since 2002, EHAP has worked with community-based organizations and local agencies to identify affected populations and provide information to them about safe fish consumption. EHAP encountered several barriers in this effort. These barriers included locating subsistence fishers, communicating information in the appropriate language, and the time-intensive nature of targeting hard-to-reach populations. While the current findings reinforce the importance of conducting this kind of outreach, EHAP does not currently have the resources to continue these time-intensive efforts.

Conclusions

-For lipophilic environmental contaminants such as PCBs, the nursing infant receives the highest dose of contaminant and is the population most sensitive to that contaminant.

-Breast milk containing PCB concentrations equal to or greater than 38 µg/g-lipid is as much as 237 times higher than background levels in the general population. However, due to the significant benefits of breast milk, breast feeding should still be recommended.

-Elevated levels of PCBs in breast milk indicate significant prenatal exposure to PCBs.

-The current fish advisory is protective of nursing infants as long as their mothers adhere to it. (See current advisory at: http://www.oregon.gov/DHS/ph/envtox/fishconsumption.shtml#Portland)

-Because remediation will not likely reduce PCB levels below health-based guidelines for several decades, effective risk mitigation depends on adherence to current fish advisories. Lack of resources for community outreach and education regarding fish advisories limits the effectiveness of those advisories to protect public health.

Recommendations

-LWG or entity designated by LWG should conduct a sustained community outreach campaign

directed towards women of childbearing age who are subsistence fishers. This campaign should promote breast feeding as the healthiest option for infants regardless of the mother's exposure scenario, promote fish as a healthy source of nutrition, and discourage eating resident fish species from Portland Harbor such as bass, carp, and catfish. To effectively encourage these health-protective behaviors, the outreach campaign should:

- Identify target populations (i.e., ethnic or cultural groups that report frequent consumption of locally caught fish)
- Characterize target populations as to:
  - Effective communication channels
  - Beliefs, attitudes, and knowledge about environmental contaminants in the fish they consume
  - Fishing practices (species and parts of fish consumed, locations fished, frequency, preparation methods)
- Develop culturally appropriate strategies and messages to encourage desired behaviors in target populations
- Implement the strategies and disseminate the messages that have been developed in the manner determined to be most effective for target populations
- Evaluate effectiveness of the campaign by assessing behavior changes in target populations

-EHAP recommends that the Lower Willamette Group and EPA consider the breast milk exposure pathway in the baseline human health risk assessment using national background breast milk PCB levels as the comparison value.

-EPA and Lower Willamette Group should include language in the baseline human health risk assessment encouraging women to continue breast feeding regardless of contaminant exposure scenario including information on the well-documented health benefits of breast feeding.

-EPA and Lower Willamette Group should use risk-based breast milk PCB concentrations derived in the baseline human health risk assessment in the development of remediation goals.

-Biomonitoring of breast milk should be implemented for women with an environmental history that includes exposure to PCBs. This biomonitoring data should be made available to health care providers to guide them in early intervention efforts to treat potential health conditions initiated by the prenatal PCB exposures indicated by elevated breast milk levels.

-EHAP strenuously encourages all women of childbearing age to abide by the current fish advisories for Portland Harbor by avoiding resident fish species from Portland Harbor. (See current advisory at: http://www.oregon.gov/DHS/ph/envtox/fishconsumption.shtml#Portland)

-EHAP recommends that all women continue to breastfeed their infants regardless of exposure situation unless directed otherwise by their physician.

Sincerely

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[2] Department of Health and Human Services, National Women's Health Information Center (2008) website http://www.4women.gov/breastfeeding/index.cfm?page=227
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